



## General

### Guideline Title

Use of vital pulp therapies in primary teeth with deep caries lesions.

### Bibliographic Source(s)

Dhar V, Marghalani AA, Crystal YO, Kumar A, Ritwik P, Tulunoglu O, Graham L. Use of vital pulp therapies in primary teeth with deep caries lesions. *Pediatr Dent*. 2017 Sep-Oct;39(5):E146-E159. [64 references]

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report [Clinical Practice Guidelines We Can Trust](#).

■■■■■= Poor ■■■■= Fair ■■■■= Good ■■■■= Very Good ■■■■= Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
■■■■■	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
NO	Multidisciplinary Group
YES	Methodologist Involvement

■ ■ ■ ■	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
■ ■ ■ ■	Search Strategy
■ ■ ■ ■	Study Selection
■ ■ ■ ■	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
■ ■ ■ ■	Grading the Quality or Strength of Evidence
■ ■ ■ ■	Benefits and Harms of Recommendations
■ ■ ■ ■	Evidence Summary Supporting Recommendations
■ ■ ■ ■	Rating the Strength of Recommendations
■ ■ ■ ■	Specific and Unambiguous Articulation of Recommendations
■ ■ ■ ■	External Review
■ ■ ■ ■	Updating

## Recommendations

### Major Recommendations

Definitions for the quality of the evidence (High, Moderate, Low, Very Low) and the strength of recommendations (Strong, Conditional) are provided at the end of the "Major Recommendations" field.

#### Question 1

In vital primary teeth with deep caries lesions requiring pulp therapy, is one particular therapy (indirect pulp therapy [IPT], direct pulp cap [DPC], pulpotomy) more successful than others?

#### Recommendation

The panel was unable to make a recommendation on superiority of any particular type of vital pulp therapy owing to lack of studies directly comparing these interventions.

#### Question 2

In vital primary teeth treated with indirect pulp treatment due to deep caries lesions, does the choice of medicament affect success?

#### Recommendation

The panel found that the success of IPT in vital primary teeth with deep caries lesions was independent of the type of medicament used, and therefore recommends that clinicians choose the medicament based on individual preferences. (Conditional recommendation, moderate-quality evidence [24 months], Low

quality evidence [48 months])

### Question 3

In vital primary teeth with deep caries lesions treated with direct pulp cap due to pulp exposure (one mm or less) encountered during carious dentin removal, does the choice of medicament affect success?

#### Recommendation

The panel found that in vital primary teeth with deep caries lesions treated with DPC due to pulp exposure (one mm or less) encountered during caries removal, the success of DPC was independent of the type of medicament (dentin bonding agents, mineral trioxide aggregate [MTA], and formocresol), and therefore recommends that clinicians choose the medicament based on individual preferences. (Conditional recommendation, very-low quality evidence)

### Question 4

In vital primary teeth with deep caries treated with pulpotomy due to pulp exposure during caries removal, does the choice of medicament or technique affect success?

#### Recommendations

The panel recommends the use of MTA in vital primary teeth with deep caries lesions treated with pulpotomy due to pulp exposure during carious dentin removal. (Strong recommendation, moderate-quality evidence)

The panel recommends the use of formocresol in vital primary teeth with deep caries lesions treated with pulpotomy due to pulp exposure during carious dentin removal. (Strong recommendation, moderate-quality evidence)

The panel recommends the use of ferric sulfate (FS) in vital primary teeth with deep caries lesions treated with pulpotomy due to pulp exposure during carious dentin removal. (Conditional recommendation, low-quality evidence)

The panel recommends the use of lasers in vital primary teeth with deep caries lesions treated with pulpotomy due to pulp exposure during carious dentin removal. (Conditional recommendation, low-quality evidence)

The panel recommends the use of sodium hypochlorite (NaOCl) in vital primary teeth with deep caries lesions treated with pulpotomy due to pulp exposure during carious dentin removal. (Conditional recommendation, very low-quality evidence)

The panel recommends the use of tricalcium silicate in vital primary teeth with deep caries lesions treated with pulpotomy due to pulp exposure during carious dentin removal. (Conditional recommendation, very low-quality evidence)

The panel recommends against the use of calcium hydroxide in vital primary teeth with deep caries lesions treated with pulpotomy due to pulp exposure during carious dentin removal. (Conditional recommendation, low-quality evidence)

### Definitions

#### Quality of Evidence Grades

Grade	Definition
High	The panel is very confident that the true effect lies close to that of the estimate of the effect.
Moderate	The panel is moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	The panel's confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low	The panel has very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

## Implications of Strong and Conditional Recommendations for Different Users of Guidelines

Implications	Strong Recommendation	Conditional Recommendation
For Patients	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
For Clinicians	Most individuals should receive the recommended course of action. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may well be useful helping individuals making decisions consistent with their values and preferences. Clinicians should expect to spend more time with patients when working towards a decision.
For Policy Makers	The recommendation can be adapted as policy in most situations including for the use as performance indicators.	Policymaking will require substantial debates and involvement of many stakeholders. Policies are also more likely to vary between regions. Performance indicators would have to focus on the fact that adequate deliberation about the management options has taken place.

## Clinical Algorithm(s)

None provided

## Scope

## Disease/Condition(s)

Deep caries lesions

## Guideline Category

Assessment of Therapeutic Effectiveness

Management

Treatment

## Clinical Specialty

Dentistry

Pediatrics

## Intended Users

Allied Health Personnel

Dentists

Public Health Departments

Students

## Guideline Objective(s)

To aid clinicians in optimizing patient care when choosing vital pulp therapies to treat children with deep caries lesions in vital primary teeth

Note: The current recommendation does not cover non-vital pulp therapies, pulp therapy for immature permanent teeth, or pulp therapy for primary teeth with traumatic injuries.

## Target Population

Children and adolescents with deep caries lesions in vital primary teeth

## Interventions and Practices Considered

- Indirect pulp treatment (IPT) using medicament (calcium hydroxide, bonding agents)
- Direct pulp capping (DPC) using medicament (calcium hydroxide, dentin bonding agents, mineral trioxide aggregate [MTA], and formocresol)
- Pulpotomy using:
  - MTA
  - Formocresol
  - Ferric sulfate (FS)
  - Lasers
  - Sodium hypochlorite (NaOCl)
  - Tricalcium silicate

Note: The use of calcium hydroxide was considered but not recommended in vital primary teeth with deep caries lesions treated with pulpotomy.

## Major Outcomes Considered

Overall success (combined clinical and radiographic) of vital pulp therapy

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

## Description of Methods Used to Collect/Select the Evidence

Methods

Evidence from "Primary Tooth Vital Pulp Therapy: a Systematic Review and Meta-Analysis" is the basis for the current guideline's recommendations.

Search Strategy and Evidence Inclusion Criteria

Since it was decided a priori to use the aforementioned systematic review, multiple literature searches were conducted in PubMed®/MEDLINE, EMBASE®, Cochrane Central Register of Controlled Trials, and trial databases to identify randomized controlled trials and systematic reviews addressing peripheral issues not covered by the review, such as patient preferences and impact of cost. The search strategy was updated by one of the authors. Title and abstract and, when warranted, full-text of studies were reviewed in duplicate by workgroup members. See the Appendix in the original guideline document for the search strategy.

Refer to the systematic review (see the "Availability of Companion Documents" field) for additional information on search strategy and inclusion and exclusion criteria.

Number of Source Documents

Forty-one articles were included in the meta-analysis.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence Grades

Grade	Definition
High	The panel is very confident that the true effect lies close to that of the estimate of the effect.
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Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The panel evaluated and voted on the level of certainty of the evidence using the Grades of Recommendation Assessment, Development, and Evaluation (GRADE) approach. The GRADE approach

recognizes the evidence quality (see the "Rating Scheme for the Strength of the Evidence" field) and certainty as high, moderate, low, and very low, based on serious or very serious issues including risk of bias, imprecision, inconsistency, indirectness of evidence, and publication bias.

## Methods Used to Formulate the Recommendations

Expert Consensus

### Description of Methods Used to Formulate the Recommendations

#### Workgroup and Stakeholders

In December, 2016, the American Academy of Pediatric Dentistry (AAPD) Board of Trustees approved a panel nominated by the Evidence-Based Dentistry Committee to develop a new evidence-based clinical practice guideline on vital pulp therapies in primary teeth with deep caries lesions. The panel consisted of pediatric dentists in public and private practice involved in research and education; the stakeholders consisted of authors of the systematic review in addition to representatives from general dentistry, governmental and non-governmental agencies, and international and specialty dental organizations.

#### Clinical Questions Addressed

The panel members used the Population, Intervention, Control, and Outcome (PICO) formulation to develop the following clinical questions that will aid clinicians in the use of vital pulp therapies in primary teeth with deep caries lesions.

In vital primary teeth with deep caries lesions requiring pulp therapy, is one particular therapy (indirect pulp treatment, direct pulp cap, pulpotomy) more successful\* than others?

In vital primary teeth treated with indirect pulp treatment due to deep caries lesions, does the choice of medicament affect success\*?

In vital primary teeth with deep caries lesions treated with direct pulp cap due to pulp exposure (one mm or less) encountered during carious dentin removal, does the choice of medicament affect success\*?

In vital primary teeth with deep caries lesions treated with pulpotomy due to pulp exposure during caries removal, does the choice of medicament or technique affect success\*?

\*Success was defined as overall success simultaneously observed both clinically and radiographically.

#### Formulation of the Recommendation

To formulate the recommendations, the panel used an evidence-to-decision framework including domains such as priority of the problem, certainty in the evidence, balance between desirable and undesirable consequences, and patients' values and preferences. The strength of a recommendation was assessed to be either strong or conditional, which presents different implications for patients, clinicians, and policy makers (see the "Rating Scheme for the Strength of the Recommendations" field).

The guidelines were formulated via teleconferences and online forum discussion with members of the workgroup. The panel members discussed all recommendations and issues surrounding the topic under review, and all significant topics such as recommendations were voted upon anonymously.

#### Understanding the Recommendations

A strong recommendation implies in most situations that clinicians should follow the suggested intervention. A conditional recommendation indicates that while the clinician may want to follow the suggested intervention, the panel recognizes that different choices may be appropriate for individual patients.

# Rating Scheme for the Strength of the Recommendations

## Implications of Strong and Conditional Recommendations for Different Users of Guidelines

Implications	Strong Recommendation	Conditional Recommendation
For Patients	Most individuals in this situation would want the recommended course of action, and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
For Clinicians	Most individuals should receive the recommended course of action. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may well be useful helping individuals making decisions consistent with their values and preferences. Clinicians should expect to spend more time with patients when working towards a decision.
For Policy Makers	The recommendation can be adapted as policy in most situations including for the use as performance indicators.	Policymaking will require substantial debates and involvement of many stakeholders. Policies are also more likely to vary between regions. Performance indicators would have to focus on the fact that adequate deliberation about the management options has taken place.

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## Cost Analysis

### Cost-effectiveness of Recommendation

Cost-effectiveness of a treatment is based on initial and possible retreatment costs. Such a cost-analysis for therapies with proven health benefits and minimal adverse effects is an important consideration for clinicians, patients, and third-party payors. This is especially important when different procedures with similar outcomes are available to treat a specific condition like in the case of vital pulp therapies. A research brief covering claims data for all children with private dental insurance lists vital pulpotomy, in primary or permanent teeth, as one of top 25 most common procedures performed in children with private dental benefits. For ages one through six years, the spending is estimated to be \$257, ranging from \$160 for children in the lowest quartile of spending to \$996 among children in the highest quartile of spending. Considering the number of pulp therapies performed on a population level, cost-effective treatment is a public health issue. However, very limited data exist on cost-effectiveness of various pulp therapies in the primary dentition. The most expensive pulp treatments and modalities with regards to initial costs are mineral trioxide aggregate (MTA) and laser. Interestingly, a German study using the Markov model followed the first permanent molar with vital asymptomatic exposed pulp treated with direct pulp cap (DPC) using MTA or calcium hydroxide over the lifetime of a 20 year old patient and reported that MTA was more cost-effective than calcium hydroxide despite higher initial treatment costs because expensive retreatments were avoided.

Refer to the original guideline document for additional information.

## Method of Guideline Validation

External Peer Review

Internal Peer Review



# Description of Method of Guideline Validation

## External Stakeholders

External and internal stakeholders reviewed the document periodically during the process of development of the guideline. Stakeholders also participated in anonymous surveys to determine the scope and outcomes of the guideline. All stakeholder comments were considered and addressed in the panel meetings. It is expected that the publication and dissemination of the guideline will generate additional dialogue, comments, and feedback from professional, academic, and community stakeholders

## Review and Feedback Integration

This guideline was continuously reviewed by external and internal stakeholders from the beginning of the process until the formulation of the guidelines. Stakeholders were invited to take part in anonymous surveys to determine the scope and outcomes of the guideline. Comment was also sought on the draft guideline. All stakeholder comments were addressed and acted upon as appropriate per group deliberation.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

Evidence from "Primary Tooth Vital Pulp Therapy: a Systematic Review and Meta-Analysis" is the basis for the current guideline's recommendations.

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Appropriate use of vital pulp therapies in primary teeth with deep caries lesions

## Potential Harms

The panel did not find sufficient evidence on adverse events related to medicaments used for indirect pulp therapy (IPT), direct pulp cap (DPC), and pulpotomy that could influence the quality of evidence. However, the panel recognizes that there may still be parental concerns regarding formocresol toxicity and discolorations associated with MTA and recommends that the clinicians should explain the evidence to parents and make decisions based on individual preferences. The panel encourages providers to closely monitor any updates from the CDC on *Mycobacterium. abscessus* infection related to pulpotomy procedures for its future implications and possible impact on the evidence.

Refer to "Potential Adverse Effects" in the original document for additional information.

# Qualifying Statements

## Qualifying Statements

Weakness of this guideline are inherent to the limitations found in the systematic review upon which this guideline is based. Limitations include failure to review non-English language studies other than those in

Spanish or Portuguese, and that the recommendations are based on combined data from studies of differing risks of bias.

# Implementation of the Guideline

## Description of Implementation Strategy

This guideline, the American Academy of Pediatric Dentistry's (AAPD's) first evidence-based guideline on pulp therapy, is published in both the journal *Pediatric Dentistry* and the AAPD's Reference Manual. By meeting the standards of the National Academy of Medicine (formerly known as the Institute of Medicine) regarding the production of clinical practice guidelines, these recommendations will be submitted to the National Guidelines Clearinghouse™ (NGC), a database of evidence-based clinical practice guidelines and related documents maintained as a public resource by the Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Services (USDHHS). Inclusion in the NGC guarantees the guidelines will be accessible and disseminated to private and public payors, policy makers, and the public. Additionally, AAPD members will be notified of the new guidelines via social media, newsletters, and presentations. The guidelines are available as an open access publication on the AAPD's Web site. Patient education materials are being developed and will be offered in the AAPD's online bookstore.

Practitioners seeking additional support implementing these guidelines are referred to the following resources:

- Treatment of Deep Caries, Vital Pulp Exposure, and Pulpless Teeth, Chapter 13, McDonald and Avery's Dentistry for the Child and Adolescent, 10th edition.
- Pulp Therapy for the Primary Dentition, Chapter 22, Pediatric Dentistry Infancy through Adolescence, 5th edition.
- Pediatric Endodontics, Chapter 26, Cohen's Pathways of the Pulp, 11th edition.
- Endodontics: Colleagues for Excellence. [www.aae.org/colleagues](http://www.aae.org/colleagues)
- Preserving Pulp Vitality, Chapter 4, The Principles of Endodontics.
- Pediatric Endodontics: Current Concepts in Pulp Therapy for Primary and Young Permanent Teeth.

## Implementation Tools

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

## IOM Domain

Effectiveness

# Identifying Information and Availability

## Bibliographic Source(s)

Dhar V, Marghalani AA, Crystal YO, Kumar A, Ritwik P, Tulunoglu O, Graham L. Use of vital pulp therapies in primary teeth with deep caries lesions. *Pediatr Dent*. 2017 Sep-Oct;39(5):E146-E159. [64 references]

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2017 Sep-Oct

## Guideline Developer(s)

American Academy of Pediatric Dentistry - Professional Association

## Source(s) of Funding

The guideline was funded by the American Academy of Pediatric Dentistry, a dental specialty organization of over 10,000 members.

## Guideline Committee

Vital Pulp Therapy Workgroup

## Composition of Group That Authored the Guideline

*Workgroup Members:* Vineet Dhar, BDS, MDS, PhD (*Vital Pulp Therapy Workgroup Chair*), clinical associate professor and chief, Division of Pediatric Dentistry, University of Maryland School of Dentistry, Baltimore, Md., USA; Abdullah A. Marghalani, BDS, MSD, DrPH, pediatric dental fellow, Division of Pediatric Dentistry, University of Maryland School of Dentistry, Baltimore, Md., USA; Yasmi O. Crystal, DMD, MSc, FAAPD, clinical associate professor of pediatric dentistry, NYU College of Dentistry, New York, N.Y., USA, and pediatric dentist in private practice, New Jersey and New York City, N.Y., USA; Ashok Kumar, DDS, MS, clinical associate professor of pediatric dentistry, The Ohio State University College of Dentistry, and director of Dental Clinic Operations, Nationwide Children's Hospital, Columbus, Ohio, USA; Priyanshi Ritwik, DDS, MS, associate professor, Department of Pediatric Dentistry, Louisiana State University School of Dentistry New Orleans, La., USA; Ozlem Tulunoglu, DDS, PhD, full-time faculty, Department of Pediatric Dentistry, Case Western Reserve University, School of Dental Medicine, Cleveland, Ohio, USA; Laurel Graham, MLS, senior evidence-based dentistry manager, American Academy of Pediatric Dentistry, Chicago, Ill., USA

## Financial Disclosures/Conflicts of Interest

Declaration of Interests

Drs. Dhar, Crystal, and Kumar serve on the editorial board of *Pediatric Dentistry*. Drs. Dhar and Marghalani are ad hoc reviewers for *Pediatric Dentistry*.

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available from the [American Academy of Pediatric Dentistry \(AAPD\) Web site](#) .

## Availability of Companion Documents

The following is available:

Coll JA, Seale NS, Vargas K, Marghalani AA, Shamali SA, Graham L. Primary tooth vital pulp therapy: a systematic review and meta-analysis. *Pediatric Dentistry*. Jan/Feb 2017;39(1):16-123. Available for purchase from the [IngentaConnect Web site](#) .

## Patient Resources

Pamphlets for patients are available for purchase from the [American Academy of Pediatric Dentistry \(AAPD\) store](#) .

## NGC Status

This NGC summary was completed by ECRI Institute on March 6, 2018. The information was verified by the guideline developer on April 16, 2018.

This NEATS assessment was completed by ECRI Institute on January 10, 2018. The information was verified by the guideline developer on April 16, 2018.

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